UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,478	07/11/2007	Timothy Crowder	9336.14	1216

98819 7590 11/14/2011

Myers Bigel Sibley & Sajovec, P.A.
PO Box 37428
Raleigh, NC 27627

EXAMINER	
LOUIS, LATOYA M	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
11/14/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

john.thallemer@sandoz.com
roshanara.diaz@sandoz.com
uspto@myersbigel.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,478	CROWDER ET AL.	
	Examiner	Art Unit	
	LaToya M. Louis	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,4,18,20,22,24,32,62 and 66-72* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,4,18,20,22,24,32,62 and 66-72* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to the amendment filed 10/5/2011. As directed by the amendment, claims 1, 4, 20, 32, 62, 66, 68, 70, and 72 have been amended, claims 2, 3, 15-17 19, 21, 23, 25-31, 33-61, and 63-65 have been cancelled, and no claims have been added. Thus claims 1, 4, 18, 20, 22, 24, 32, 62, and 66-72 are currently pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (2002/0134382 A1) in view of Ede (7,588,030).

Regarding claim 1 Snow teaches the apparatus and method wherein in figs. 1a and 1e a multi-dose blister package having a plurality of blisters thereon and adapted for use in an inhaler, comprising: a polymeric frame member (i.e. 108) having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (148,152), a respective gap space configured to define at least a portion of a sidewall of a respective blister, wherein the frame gap spaces are circumferentially spaced apart through- apertures arranged in two substantially concentric rows ([0070]); and a planar floor (layer 104 as floor depending on the orientation of the device. For example, when the blister pack is placed upside down, planar sealant layer 104 acts as the floor) comprising a flexible sealant material ([0063]) directly attached to the bottom surface of the frame member so that the floor extends under each gap space to define a bottom of each blister; and a ceiling comprising a flexible material ([0077] and [0086] discloses semi-rigid material which is more rigid than foil but still relatively flexible [0131]) directly attached to the top surface of the frame member so that the ceiling extends above each gap space to define a top of each blister (as shown, when the blister pack is placed upside down, the layer 112 acts as the ceiling), wherein each blister holds dry powder medicament (216) and, when sealed, is devoid of any movable internal component therein such that the dry powder can directly contacts the frame sidewalls of a respective blister (fig. 4a), and wherein the blister package has an annular shape with an open center (136).

Snow teaches a frame (108) but does not specifically disclose that the frame is lightweight, rigid, and at least 10 times thicker than the thickness of the floor and the ceiling. However, Ede teaches in figs. 1 and 2 a rigid lightweight frame (10) having a thickness 10 times greater than the floor (14) or the ceiling (12). It would have been obvious to one of ordinary skill

in the art at the time the invention was made to modify the frame of Snow with a rigid thicker frame as taught by Ede to allow for larger numbers of doses to be contained as disclosed by Ede in col. 3 lines 36-40.

5. Claims 1, 4, 18, 20, 22, 32, 62, 66, 67, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. (WO 01/68169) in view of Ede.

Regarding claims 1, 32, 62 and 69, Hickey teaches from figs. 7 and 8 the apparatus and method including a multi-dose blister package having a plurality of blisters (40) thereon and adapted for use in an inhaler, comprising: a planar sealant floor (as shown in figs. 7 and 8, the combination of barrier 35 and pad 25u as floor which is planar. Alternatively, sealant layer 45 as planar floor, depending on the orientation of the device) comprising a flexible material (page 19 lines 29-31) and the floor extends under each blister (40) to define a bottom of each blister wherein the blisters are circumferentially spaced apart (Fig. 6B) arranged in two substantially concentric rows (As shown in figs. 6A and 6B, the blisters are arranged in concentric rows); a planar sealant ceiling (sealant layer 45 and pad 25b as ceiling which is shown as planar in the embodiments on figs. 7 and 8. Alternatively, the combination of barrier 35 and pad 25u as ceiling depending on the orientation of the device) comprising a flexible material (page 21 line 25 discloses that the ceiling 45 can be torn open) and the ceiling extends above each blister to define a top of each blister wherein each blister holds dry powder medicament (30) and when sealed is devoid of any movable component such that dry powder is able to contact this sides of a respective blister (as shown, in fig. 3a, the powder 30 is able to contact the sides of the blister) and wherein the blister package has an annular shape with an open center (20o).

Hickey teaches in fig. 6B circumferentially spaced blisters (40) filled with dry powder (30) directly contacting the sides of each blister and an inhaler mounting member (10) attached to the blister package and residing upward through a center space (20o) of the blister but does not teach a rigid lightweight frame member having opposing top and bottom surfaces with a plurality of spaced apart gap spaces, a respective gap space configured to define at least a portion of a sidewall of a respective blister wherein the gap spaces are through apertures, and wherein a floor is directly attached to the bottom of the frame member and a ceiling is directly attached to a top of the frame member. However, Ede teaches in figs. 1d, 5, and 8 a rigid lightweight polymeric frame member (10) (col. 6 lines 22-35) having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (18), a respective gap space configured to define at least a portion of a sidewall (16) of a respective blister (20), a floor (60) directly attached to the bottom of the frame member, a ceiling (59) directly attached to the top surface of the frame member so that the ceiling extends above each gap space to define a top of each blister so that the inhaler mounting member resides upward through a center space of the annular ceiling, floor, and frame, the frame member (10) having a thickness that is at least 10 times greater than the thickness of the floor (i.e. 14) and ceiling (i.e. 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blister pack of Hickey with the frame as taught by Ede to allow for larger numbers of doses to be contained as taught by Ede in col. 3 lines 36-40.

Regarding claim 4, Hickey teaches from figs. 3, 4, 7, and 8 a bolus quantity of dry powder (30) disposed in respective blisters.

Regarding claim 18, the modified Hickey teaches in fig. 1 of Ede that the floor (14) and the ceiling (12) have substantially the same thickness and that the frame member is a unitary polymer structure having increased structural rigidity relative to the floor and ceiling (col. 6 lines 22-23 of Ede discloses that the frame can be a polymer and col. 7 line 43 of Ede discloses that the sheets i.e. 12 can be made from foil).

Regarding claim 20, Hickey teaches in fig. 3A and 10A wherein the ceiling (the combination of barrier 35, pads 25u, 25b and substrate layer 28 as ceiling or only substrate 28 as ceiling) comprises a generally planar sealant layer (i.e. barrier 35 or substrate 28 as sealant layer) sealably attached to the blister to define a ceiling when the device is an upside-down orientation.

Regarding claim 22, Hickey teaches that the ceiling (45) is a sealant polymer coating (page 6 line 22) and can thus be deduced to be moisture resistant. In addition page 15 lines 25-26 disclose moisture resistant barriers. However, Hickey does not specifically disclose that the ceiling comprises foil. Ede however teaches a ceiling with moisture resistant foil (col. 4 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the ceiling with polymer coating of Hickey with the moisture resistant foil as taught by Ede to provide increased sealing ability with the device and increased moisture resistance. It is noted that aluminum foil with polymer coatings are old and well known in the art.

Regarding claims 24 and 72, Hickey teaches from figs. 3, 4, 7, and 8 that the combination of barrier 35, pads 25u,25b and substrate layer 28 as floor or sealant layer 45 as floor, depending on the orientation of the device are both substantially planar and the modified Hickey discloses

that opposing sidewalls of a respective gap space are inclined so that the sidewalls taper farther away from each other from a bottom to top portion thereof (col. 10 lines 28-37 of Ede disclose that the walls can be angled 3 degrees from 90 with a wider opening at the top) and that the thickness of the frame is at least 15 times greater than the floor or ceiling (Ede discloses in col. 8 line 60, col. 9 line 4, 56-58 that the frame could have a thickness of about 3mm-5mm. Since the lidding foils of the floor and ceiling are typically 0.2mm, the frame is at least 15 times thicker than the foil.

Regarding claim 66, Hickey teaches from figs. 3, 4, 7, and 8 that the combination of barrier 35, pads 25u, 25b and substrate layer 28 as floor or sealant layer 45 as floor, depending on the orientation of the device are both substantially planar and the modified Hickey discloses that the frame member comprises a molded polymer (col. 6 lines 22-23 of Ede) with sidewalls that are about 2mm deep (col. 9 lines 56-57 of Ede).

Regarding claim 67, the modified Hickey teaches from fig. 1 of Ede that the frame member apertures are substantially circular when viewed from the top and bottom).

Regarding claim 71, the modified Hickey discloses that the frame member gap spaces are about 2mm long (col. 9 line 14 discloses that the gaps can be about 2mm long along the vertical axis).

6. Claims 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey in view of Ede, as applied to claim 1 above, and further in view of Casper (2007/0181124).

Regarding claims 68 and 70, the modified Hickey discloses that the walls can be inclined with rounded end (col. 9 lines 56-58 of Ede) but does not specifically disclose that the walls can be coned shaped having substantially constant angles of inclination of between about 20-40 degrees from a bottom to a top portion thereof. However, Casper teaches in figs. 5b and 6b side walls of a blister that are coned shaped with an angle of inclination of approximately 40-45 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the sidewalls of the modified Hickey with the cone shaped angle of inclination as taught by Casper to facilitate dosage removal. In addition such a change would be considered a design choice, requires a mere change in shape of a component, and would function equally well. Hickey teaches the rest of the limitations as claimed. See the rejection of claim 66 above.

Response to Arguments

7. Applicant's arguments as it relates to the newly added claim limitations have been considered and have been addressed in the new grounds of rejection above.

8. Applicant's arguments filed 8/4//2011 have been fully considered but they are not persuasive.

Applicant argues on page 8 first paragraph that "one of ordinary skill in the art would not have been motivated to use the frame of Ede with the lower layer of Snow." Examiner disagrees because Snow teaches a frame 108 that is used with the lower layer (i.e. 112) of Snow. Ede also teaches a frame member 10 which is thicker to allow larger doses of medicament. Thus one of

ordinary skill in the art upon seeing the frame of Ede would be able to modify the frame of Snow to be thicker to increase entrainment and flow delivery and to allow for larger doses to be contained.

Applicant also argues on page 8 3rd paragraph and page 9 2nd paragraph that the claimed design teaches a specific moisture path. The arguments are irrelevant however because no limitation relating to a moisture path is found in the claim language.

Regarding applicant's arguments on page 9 2nd paragraph, applicant argues "there is no motivation to modify Hickey as alleged." Examiner respectfully disagrees. One of ordinary skill in the art upon seeing the frame thickness of Ede would be able to provide the blister pack of Hickey with the frame as taught by Ede to provide the advantage of allowing larger doses to be contained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya M. Louis whose telephone number is (571)270-5337. The examiner can normally be reached on Monday-Friday, 8:30am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LaToya M Louis/
Examiner, Art Unit 3771
11/3/2011

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771